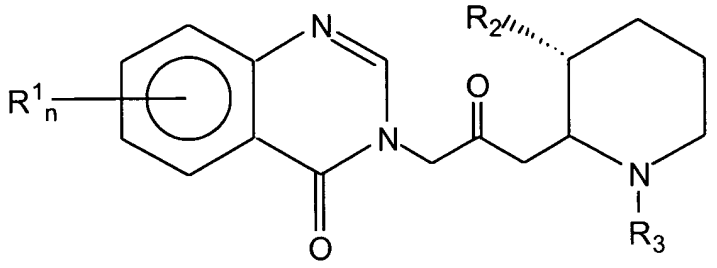
Amendments To The Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (previously presented) A polymeric delivery system for sustained release administration of a quinazolinone derivative of formula (I)



(I)

wherein: n=1-2

R_1 which may be the same or different at each occurrence is a member of the group consisting of hydrogen, halogen, nitro, benzo, lower alkyl, phenyl and lower alkoxy;

R_2 is a member of the group consisting of hydroxy, acetoxy and lower alkoxy;

R_3 is a member of the group consisting of hydrogen and lower alkenoxy-carbonyl; and pharmaceutically acceptable salts thereof, wherein the quinazolinone is released at a therapeutically effective dose for a period of at least one month.

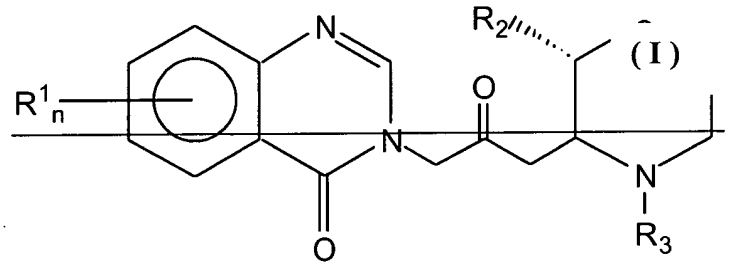
2. (previously presented) The polymeric delivery system of claim 1 wherein the delivery system is formulated for local administration or topical administration to a target site in a subject.

3. (previously presented) The delivery system of claim 2, wherein the route of administration is selected from implantation, subcutaneous injection or deposition within a body cavity.

4. (previously presented) The delivery system of claim 1, wherein the quinazolinone derivative of formula (I) is halofuginone.

5. (currently amended) The delivery system of claim 3, wherein the delivery system is formulated as an implant, with the proviso that said implant does not comprise a stent ~~other than as a coating for a stent~~.

6. (currently amended) A polymeric delivery system according to claim 1, comprising ~~for sustained release of a quinazolinone derivative of formula (I):~~



~~wherein: n=1-2~~

~~R_1 which may be the same or different at each occurrence is a member of the group consisting of hydrogen, halogen, nitro, benzo, lower alkyl, phenyl and lower alkoxy;~~

~~R_2 is a member of the group consisting of hydroxy, acetoxy and lower alkoxy;~~

~~R_3 is a member of the group consisting of hydrogen and lower alkenoxy carbonyl; and pharmaceutically acceptable salts thereof;~~

~~the polymeric delivery system comprising~~ biocompatible two-phase polymeric beads comprising a core compartment, said core compartment comprising a water-in-oil emulsion surrounded by a polymeric shell compartment comprising a biocompatible polymer, wherein the discontinuous aqueous phase of the core

compartment of the polymeric beads comprises the quinazolinone derivative of formula (I).

7. (previously presented) The delivery system of claim 6, wherein the biocompatible polymer is a natural or synthetic hydrophilic polymer.

8. (previously presented) The delivery system of claim 7, wherein the biocompatible hydrophilic polymer is a polysaccharide or a protein.

9. (currently amended) The delivery system of claim 8, wherein the polysaccharide is selected from the group consisting of: alginate, dextran, cellulose, cellulose derivatives, dextran sulfate, chondroitin sulfate, heparan sulfate, heparin, keratan sulfate, dermatan sulfate, and algal polyglycan sulfates.

10. (canceled)

11. (currently amended) The delivery system of claim 8, wherein the protein is selected from the group consisting of: gelatin, collagen, elastin, fibrin and albumin.

12. (canceled)

13. (previously presented) The delivery system of claim 6, wherein the quinazolinone derivative of formula (I) is halofuginone.

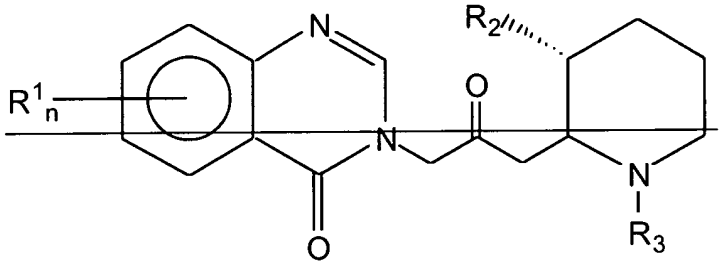
14. (currently amended) The delivery system of claim 6, wherein the quinazolinone derivative of formula (I) is released at a therapeutically effective concentration for a time period ranging from [[a]] several days to [[a]] several months.

15. (previously presented) The delivery system of claim 6, wherein the delivery system is formulated for local administration or topical administration to a target site.

16. (currently amended) The delivery system of claim 15, wherein the route of administration is selected from the group consisting of implantation, subcutaneous injection or deposition within a body cavity.

17. (currently amended) The delivery system of claim 6, wherein the polymeric beads are dispersed within an oil-based formulation or water-based selected from the group consisting of an oily suspension, emulsion, cream and gel.

18. (currently amended) A polymeric delivery system according to claim 1 ~~for local sustained release of a quinazolinone derivative of formula (I):~~



(I)

~~wherein: n=1-2~~

~~R_1 which may be the same or different at each occurrence is a member of the group consisting of hydrogen, halogen, nitro, benzo, lower alkyl, phenyl and lower alkoxy;~~

~~R_2 is a member of the group consisting of hydroxy, acetoxy and lower alkoxy;~~

~~R_3 is a member of the group consisting of hydrogen and lower alkenoxy carbonyl; and pharmaceutically acceptable salts thereof;~~

~~the polymeric delivery system~~ comprising a biocompatible polymeric film wherein the quinazolinone derivative of formula (I) is homogeneously dispersed within the film.

19. (currently amended) The delivery system of claim 18, wherein the biocompatible polymer is a selected from the group consisting of a synthetic biodegradable and a synthetic non-biodegradable polymer.

20. (currently amended) The delivery system of claim 19, wherein the synthetic polymer is selected from: polyacrylic acid polymers, polylactic acid polymers, polycaprolactone polymers, polyglycolic acid and ~~various~~ copolymers thereof.

21. (canceled)

22. (previously presented) The delivery system of claim 18, wherein the polymeric film is a coating of an article.

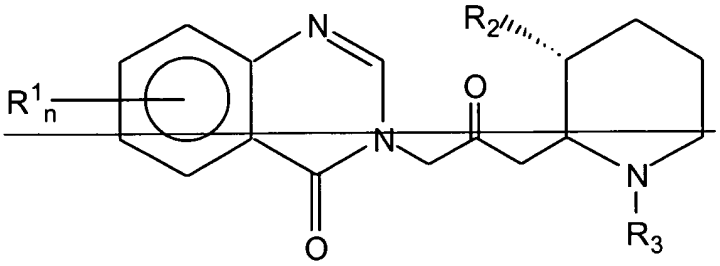
23. (previously presented) The delivery system of claim 18, wherein the quinazolinone derivative of formula (I) is halofuginone.

24. (currently amended) The delivery system of claim 18, wherein the quinazolinone derivative of formula (I) is released at a therapeutically effective concentration for a time period ranging from [[a]] several days to [[a]] several months.

25. (currently amended) The delivery system of claim 18, wherein the delivery system is ~~suitable~~ adapted for a route of administration selected from subcutaneous implantation and deposition within a body cavity.

26. (currently amended) The delivery system of claim 18, wherein the delivery system is ~~suitable~~ adapted for application topically at a target site of a subject.

27. (currently amended) A polymeric delivery system according to claim 1 ~~for sustained release of a quinazolinone derivative of formula (I)~~



(I)

~~wherein: n=1-2~~

~~R_1 which may be the same or different at each occurrence is a member of the group consisting of hydrogen, halogen, nitro, benzo, lower alkyl, phenyl and lower alkoxy;~~

~~R_2 is a member of the group consisting of hydroxy, acetoxy and lower alkoxy;~~

~~R_3 is a member of the group consisting of hydrogen and lower alkenoxy carbonyl; and pharmaceutically acceptable salts thereof;~~

~~the delivery system~~ comprising a polymeric complex comprising at least one type of biocompatible negatively-charged polymeric molecule conjugated through electrostatic interactions to the quinazolinone derivative of formula (I), said quinazolinone derivative of formula (I) having a positive charge at physiological pH.

28. (currently amended) The delivery system of claim 27, wherein the negatively charged biocompatible polymer [[is]] comprises a synthetic or natural biocompatible polymer.

29. (currently amended) The delivery system of claim 28, wherein the synthetic or natural polymer is selected from the group consisting of polyacrylic acid polymers, alginate polymers, polylactic acid polymers, polyglycolic acid and ~~various~~ copolymers thereof.

30. (canceled)

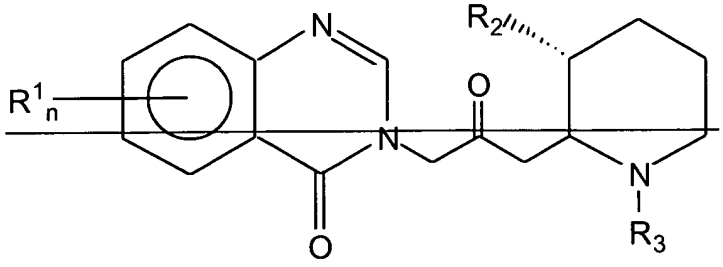
31. (previously presented) The delivery system of claim 27, wherein the quinazolinone derivative of formula (I) is halofuginone.

32. (currently amended) The delivery system of claim 27, wherein the quinazolinone derivative of formula (I) is released at a therapeutically effective concentration for a time period ranging from [[a]] several days to [[a]] several months.

33. (currently amended) The delivery system of claim 27, wherein the delivery system is ~~suitable~~ adapted for a route of administration selected from subcutaneous implantation and deposition within a body cavity.

34. (currently amended) The delivery system of claim 27, wherein the delivery system is ~~suitable~~ adapted for application topically at a target site of a subject.

35. (currently amended) A polymeric delivery system according to claim 1 ~~for sustained release of a quinazolinone derivative of formula (I):~~



(I)

~~wherein: n=1-2~~

~~R_1 which may be the same or different at each occurrence is a member of the group consisting of hydrogen, halogen, nitro, benzo, lower alkyl, phenyl and lower alkoxy;~~

~~R_2 is a member of the group consisting of hydroxy, acetoxy and lower alkoxy;~~

~~R_3 is a member of the group consisting of hydrogen and lower alkenoxy carbonyl; and pharmaceutically acceptable salts thereof,~~ ~~the polymeric delivery system comprises~~ comprising biocompatible polymeric beads in suspension, wherein the polymeric beads comprise the quinazolinone derivative of formula (I).

36. (previously presented) The delivery system of claim 35, wherein the biocompatible polymer is a natural or synthetic hydrophilic polymer.

37. (currently amended) The delivery system of claim 36, wherein the biocompatible natural polymer is selected from the group consisting of a polysaccharide and a protein.

38. (currently amended) The delivery system of claim 37, wherein the polysaccharide is selected from the group consisting of: alginate, dextran, cellulose, cellulose derivatives, dextran sulfate, chondroitin sulfate, heparan sulfate, heparin, keratan sulfate, dermatan sulfate, and algal polyglycan sulfates.

39. (canceled)

40. (currently amended) The delivery system of claim 37, wherein the protein is selected from the group consisting of: gelatin, collagen, elastin, fibrin and albumin.

41. (canceled)

42. (previously presented) The delivery system of claim 35, wherein the quinazolinone derivative of formula (I) is halofuginone.

43. (currently amended) The delivery system of claim 35, wherein the quinazolinone derivative of formula (I) is released at a

therapeutically effective concentration for a time period ranging from [[a]] several days to [[a]] several months.

44. (currently amended) The delivery system of claim 35, wherein the delivery system is ~~suitable~~ adapted for a route of administration selected from the group consisting of implantation, subcutaneous injection and deposition within a body cavity.

45. (previously presented) The delivery system of claim 35, wherein the delivery system is formulated for topical administration to a target site in a subject.

46. (currently amended) The delivery system of claim 35, wherein the polymeric beads are dispersed within an oil-based or water-based formulation selected from the group consisting of an oily suspension, emulsion, cream or gel.

47. (currently amended) A method of preparing the biocompatible polymeric beads of claim 6 comprising:

mixing an aqueous suspension of the quinazolinone derivative of formula (I) in an oily phase to form a water-in-oil emulsion;
homogenizing said emulsion ~~the mixture of step (a)~~;
applying a polymeric shell around small droplets of the emulsion by ~~means of~~ core/shell extrusion, and
solidifying the shell to form two phase core-and-shell-structured polymeric beads.

48. (currently amended) A method of preparing the polymeric film of claim 18 comprising:

[[a.]] dissolving the quinazolinone derivative of formula (I) in an organic solvent to form a drug solution;
[[b.]] mixing the polymer in ~~suitable~~ a solvent to form a polymeric solution;

[[c.]] mixing the drug solution with the polymeric solution; and

[[d.]] evaporating the polymer solvent to form the polymeric films comprising said quinazolinone derivative of formula (I) homogenously dispersed therein.

49. (currently amended) A method of preparing the biocompatible delivery system of claim 27 comprising:

[[a.]] dissolving the quinazolinone derivative of formula (I) in an aqueous phase to form a drug solution;

[[b.]] mixing the polymer in ~~suitable~~ an aqueous phase to form a polymeric solution;

[[c.]] mixing the drug solution with the polymeric solution for sufficient time to form polymeric complexes; and

[[d.]] precipitating the polymeric complexes.

50. (currently amended) A method of preparing the biocompatible delivery system of claim 35 comprising:

[[a.]] suspending the quinazolinone derivative of formula (I) in an aqueous solution to form a drug suspension;

[[b.]] mixing the polymer in ~~suitable~~ a solvent to form a polymeric solution;

[[c.]] mixing the polymeric solution with a cross linking agent and the drug suspension to form polymeric beads comprising said quinazolinone derivative of formula (I).

51-66 (canceled).

67. (previously presented) An implant comprising the polymeric delivery system of claim 6.

68. (previously presented) An implant comprising the polymeric delivery system of claim 18.

69. (previously presented) An implant comprising the polymeric delivery system of claim 27.

70. (previously presented) An implant comprising the polymeric delivery system of claim 35.